

## REMARKS

### *Status of the Claims*

Claims 9, 10, 14-16, 34 and 40-45 are pending in the application.

Claims 9, 10, 14-16, 34 and 40-45 have been rejected.

By way of this amendment, claim 9 has been amended, claims 10 and 14 have been canceled and new claims 46-48 have been added

Upon entry of this amendment, claims 9, 15, 16, 34 and 40-48 will be pending.

### *Summary of the Amendment*

Claim 9 has been amended to incorporate the limitations of claims 10 and 14 into claim 9. Claims 10 and 14 have been canceled as redundant in view of the amendment of claim 9. As amended, claim 9 contains the subject matter deemed enabled and non-obvious in the Official Action.

New claim 46 corresponds to claim 44 except it is dependent on claim 45.

New claim 47 corresponds to claim 16 except it is dependent on claim 34.

Support for the amendment is found throughout the specification and claims as filed. No new matter has been added.

### *Double Patenting*

It is noted that if claim 10 is deemed allowable, claim 41 would be objected to under 37 CFR 1.75. In view of the cancellation of claim 10, the issue is moot.

### *Rejection Under 35 U.S.C. 112, first paragraph*

Claims 9, 10, 14-16, and 34 stand rejected based upon 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the enablement requirement. The Office notes that the rejection has been withdrawn with respect to claim 10 but states in the next sentence that claims

Bonadio refers to SV40 polyA signal sequence.

It is asserted that if the claimed invention would have been obvious to one skilled in the art in view of the cited art. It is asserted that it would be obvious to those skilled in the art to choose a site local to a lymph node to inject plasmid DNA by IM injection in order to deliver it to a lymph node local to the injection site.

Applicants respectfully disagree. It is well settled that it is necessary to identify the reason why a person of ordinary skill in the art would have combined the prior art elements in the manner claimed. While Jolly refers to expression of certain proteins in macrophage, Jolly does not describe how to deliver DNA to macrophage cells. Jolly does not expression of DNA in macrophage cells of genes which include signals for secretion of protein produced. Hedley refers to the use of microparticles for delivery into macrophage cells, not delivery of proteins to lymph nodes. None of the references teach or suggest delivery of proteins to lymph nodes. Only with impermissible hindsight would one conclude that one skilled in the art would combine the references. Applicants respectfully urge that the combination of references does not render any of the claims obvious.

Applicants respectfully urge that claims 16, 34, 44 and 45 are further distinguishable over the cited art in that the combination of art conspicuously lacks any description of the subject matter of these claims. Claims 16 and 44 specifically refer to the administration of DNA in combination with bupivacaine. Nothing in the cited references remotely discloses this claimed subject matter. Claims 34 and 45 refer to intramuscular injection. None of the cited references disclose this claimed subject matter. Applicants urge that there is nothing in the combination of references which disclose that DNA can be delivered to macrophage cells by intramuscular injection. Neither Jolly nor Hedley nor any other art discloses that intramuscular injection of DNA can be used to deliver DNA to macrophage, and thereby deliver proteins to lymph nodes.

Applicants respectfully request that the rejection under 35 U.S.C. § 103 be withdrawn.

9, 10, 14-16, and 34 stand rejected (Page 3 of the Official Action). In view of the reasoning provided, the listing of claim 10, as well as claim 34, appears to be an error since the rejection is based upon an assertion that the claims include topical administration and claims 10 and 34 refer to specific modes of administration other than topical.

The subject matter of claim 10 (and claim 14) has been incorporated into claim 9, from which claims 15, 16 and 34 each depend. Accordingly, as amended, claim 9 and claims 15, 16 and 34 are enabled. The rejection is moot. Applicants respectfully request that the rejection under 35 U.S.C. § 112, first paragraph be withdrawn.

***Rejection Under 35 U.S.C. 103***

Claims 9, 10, 15-16, 34 and 40-45 stand rejected based upon 35 U.S.C. § 103, as allegedly being unpatentable over U.S. Patent App. No. 2004/0063652 to Jolly, Kataoka et al (1997) J Biol. Chem, 272(29):18209-15, U.S. Patent No. 5,783,567 to Hedley et al., Samlowski et al (1988) Regional Immunology, 1(1):41-55 and U.S. Patent No. 5,763,416 to Bonadio et al. It is stated that the rejection has been made in view of the recent decision by the U.S. Supreme Court in KSR v. Teleflex, 82 U.S.P.Q.2d 1385 (2007).

The Official Action does not indicate a rejection of claim 14 under 35 U.S.C. § 103. If this subject matter is deemed free of the art, the incorporation of the subject matter of claim 14 into claim 9, from which claims 15, 16 and 34 each depend, renders claim 9 and claims 15, 16 and 34 are non-obvious in view of the cited art.

Jolly refers to introducing DNA that encodes enzymes which enhance antiviral effects of certain antiviral drugs into macrophage to make the cells more vulnerable to antiviral compounds.

Kataoka refers to the human CD156 including its promoter.

Hedley refers to phagocytosis by macrophage of microparticles administered subcutaneously. The macrophage are indicated to drain to lymph nodes.

Samlowski refers to drainage of macrophage to lymph nodes local to injection sites.

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*Conclusion*

Claims 9, 15, 16, 34, and 40-48 are in condition for allowance. A notice of allowance is earnestly solicited.

The Commissioner is hereby authorized to charge any deficiencies of fees and credit of any overpayments to Deposit Account No. 50-0436.

Respectfully Submitted,

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